



APR 1 2 2004

K040593

Traditional 510(k) Premarket Notification

### Summary of Safety and Effectiveness

**Submitter:** Zimmer, Inc.  
P.O. Box 708  
Warsaw, IN 46581-0708

**Contact Person:** Laura D. Williams, RAC  
Sr. Associate, Regulatory Affairs  
Telephone: (574) 372-4523  
Fax: (574) 372-4605

**Date:** March 5, 2004

**Trade Name:** *Zimmer®* Periarticular Locking Plates

**Classification Name:** Plate, Fixation, Bone  
Screw, Fixation, Bone

**Classification Reference:** 21 CFR § 888.3030,3040

**Predicate Device:** *Zimmer ECT®* Internal Fracture Fixation System,  
Preamendment Device  
  
Synthes Locking Distal Radius Plating System,  
K012114, cleared 9-28-01  
  
Synthes Distal Radius Plate System, K982732,  
cleared 10-8-98

**Device Description:** The *Zimmer* Periarticular Locking Plate System is a plate and screw system intended for internal fracture fixation. The low-profile periarticular locking plate is anatomically contoured and has threaded holes which accept locking screws to create a stable, fixed angle construct.

**Intended Use:** The *Zimmer* Periarticular Locking Plate System is indicated for temporary internal fixation and stabilization of osteotomies and fractures, including comminuted fractures, supracondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions.

**Comparison to Predicate Device:**

The Zimmer Periarticular Locking Plate System has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices.

**Performance Data:**

The results of non-clinical (laboratory) performance testing demonstrate that the device is safe and effective.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Laura D. Williams, RAC  
Senior Associate, Regulatory Affairs  
Zimmer, Inc.  
P.O. Box 708  
Warsaw, Indiana 46581-0708

Re: K040593

Trade/Device Name: Zimmer® Periarticular Locking Plate System  
Regulation Numbers: 21 CFR 888.3030, 21 CFR 888.3040  
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Codes: HRS, HWC  
Dated: March 5, 2004  
Received: March 8, 2004

Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

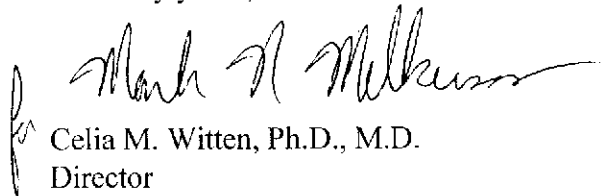
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -- Ms. Laura D. Williams, RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over a printed name. To the left of the signature is a small, stylized mark that looks like a lowercase "f" or a checkmark.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

**510(k) Number (if known):**

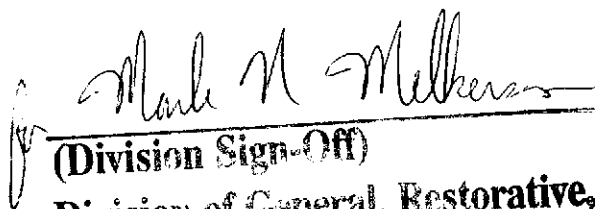
**Device Name:**

*Zimmer®* Periarticular Locking Plate System

**Indications for Use:**

The Periarticular Locking Plate System is indicated for temporary internal fixation and stabilization of osteotomies and fractures, including:

- Comminuted fractures
- Supracondylar fractures
- Intra-articular and extra-articular condylar fractures
- Fractures in osteopenic bone
- Nonunions
- Malunions



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

**510(k) Number** K040593

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)